



R.E.D. FACTS

3-Iodo-2-propynyl butylcarbamate (IPBC)

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing or reassessing tolerances.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2725, 3-Iodo-2-propynyl butylcarbamate (IPBC).

Use Profile

IPBC is a fungicide/antimicrobial used as a preservative in paint, adhesives, emulsions, metal cutting fluids, oil recovery drilling mud/packer fluids, plastics, textiles, inks, paper coatings, and wood products. It is also used in residential settings as a wood preservative stain to combat wood rot/decay, and as a preservative in paints. IPBC is also applied to heating, ventilation, and air conditioning (HVAC) ducts and equipment to control mold and fungi.

Regulatory History

IPBC was first registered in the United States in 1975 for use as a disinfectant, fungicide and algicide. A September 1993 reregistration data call-in (DCI) was sent to the pesticide manufacturer requesting technical product chemistry, ecological effects, and environmental fate studies. There are currently 53 registered pesticide products containing IPBC.

Human Health Assessment

Toxicity

In studies using laboratory animals, IPBC has been shown to be practically non-toxic for dermal irritation, and has been placed in Category IV (the lowest of four categories) for this effect. It is slightly toxic for acute oral, dermal, and inhalation exposure, and has been placed in Toxicity Category III for these effects. IPBC is highly toxic for eye irritation and has been classified as Category I for this effect.

IPBC is not considered a developmental toxicant or a mutagen. The Agency has classified IPBC as "not likely" to be a carcinogen using the Agency's revised Guidelines for Carcinogen Risk Assessment. In the context of the revised guidelines this classification was based on: a) the lack of a carcinogenic response for combined adenoma/carcinoma of the liver in male mice as a result of the re-evaluation of the tumor incidence in the mouse carcinogenicity study; b) the lack of carcinogenic response in female mice and in male or female rats; c) the absence of mutagenic activity; and d) the absence of data suggesting formation of a reactive metabolite of IPBC which might be responsible for initiation of the tumors observed.

Dietary Exposure

Since IPBC is not currently approved for use on food or feed crops, no dietary exposure to IPBC residues is expected.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) and other people may be exposed to IPBC formulations during and after application. The Agency has identified two levels of exposure, to primary handlers -- persons directly handling IPBC pesticide products; and to secondary handlers -- persons handling manufactured products, such as paints and adhesives, to which IPBC has been added as a preservative.

Human Risk Assessment

IPBC generally is of low acute toxicity. Using the revised Guideline for Carcinogen Risk Assessment, the Agency has classified IPBC as "not likely" to be carcinogenic. Dietary exposure to IPBC residues in foods is not expected to occur since there are no currently registered uses for IPBC on food or feed products.

The Agency assessed the risk resulting from short-term and intermediate-term IPBC exposures associated with occupational and

homeowner handlers (primary and secondary). The Agency also assessed the risk resulting from chronic IPBC exposures to certain occupational handlers (primary and secondary). The NOEL for short and intermediate-term exposure is 200 mg/kg/day (from the subchronic dermal rat study) and the NOEL for chronic exposures is 20 mg/kg/day (from the chronic rat study).

EPA assessed risks to handlers using margins of exposure (MOEs). The MOE is a ratio of the NOEL to the daily dose. EPA generally is not concerned with MOEs greater than or equal to 100. The MOEs for all IPBC occupational and homeowner scenarios for which data are available are acceptable, except for occupational painters using airless or compressed air sprayers; their exposure becomes acceptable when PPE (long-sleeve shirt, long pants, shoes, socks, and chemical resistant gloves) is used. EPA's regulatory authority does not encompass requiring label statements for paints. However, EPA believes that occupational painters would likely wear appropriate PPE. Furthermore, painters are not likely to use only paints containing IPBC, nor are they likely to use only airless or compressed air sprayers.

Due to the lack of exposure data for IPBC, the potential risks related to several exposure scenarios cannot be assessed at this time. These include:

- exposure to workers during industrial treatments to milled forest products, including post application exposure to workers handling or processing treated wood products;
- exposure to workers applying IPBC products to heating, ventilation, and air conditioning (HVAC) ducts or equipment, and post application exposure to occupants of areas where HVAC systems have been treated;
- post application exposure to persons handling and using textiles, such as carpets, drapes, shower curtains, and canvas, to which IPBC has been applied; and
- exposure to non-industrial, occupational workers and homeowners applying IPBC products to wood by dipping, using a pad, or any method other than a brush, roller, and airless or compressed air sprayer.

The Agency is therefore requiring additional data to characterize the risk associated with these exposure scenarios before a reregistration eligibility decision can be made. For all other uses, exposure and risk to workers will be adequately mitigated by the use of additional PPE as required by this RED. Additional confirmatory data are also being required to satisfy the following guidelines: 81-8 (Acute Rat Neurotoxicity with cholinesterase) and 82-7 (90-day Rat Neurotoxicity with cholinesterase).

Other Considerations

Because IPBC currently has no food uses and no tolerances have been established, the specific determinations outlined in the Food Quality Protection Act of 1996 are not required for this chemical. Nevertheless, EPA has considered available data relating to the special sensitivity of infants and children, the potential for aggregate exposures to IPBC, and the potential for

cumulative effects from IPBC and other chemicals with a common mode/mechanism of toxicity because children and other individuals could be exposed to this compound in non-occupational settings.

Based on reliable data for pre- and post-natal effects indicating no special sensitivity of young organisms to IPBC, the Agency has concluded that an additional uncertainty factor need not be applied to the short- and intermediate-term NOELs used in the IPBC risk assessments.

Because it degrades rapidly, IPBC is not likely to be found in drinking water and no dietary exposure is expected. EPA assumes that handling and applying paint would be the reasonable worst case exposure scenario for homeowners (non-occupational exposure). Because MOEs for this worst case exposure are high, EPA believes that aggregate exposures to other sources of IPBC in the home are not likely to be of concern.

The Agency has not yet determined whether it is appropriate to consider exposure from other carbamates with IPBC in order to address potential cumulative effects. However, based on the high MOEs for homeowner applicators, the lack of food uses, unlikely residues in drinking water, and the high NOEL for dermal exposure (the most likely route), the Agency believes that it is reasonable to assume that the contribution of IPBC exposure to the risks from other carbamate pesticides is likely to be minimal considering currently registered IPBC uses.

Environmental Assessment

The Agency has adequate data to assess the toxicity of IPBC to nontarget organisms.

Environmental Fate

A qualitative environmental fate assessment has been completed for IPBC. Submitted environmental fate and transport data suggest that IPBC is non-persistent and mobile in soil and aquatic environments. Because it degrades rapidly, IPBC should not pose a contamination threat to surface and ground water.

Ecological Effects

IPBC is slightly toxic to practically nontoxic to avian species on an acute oral and subacute dietary basis. IPBC is slightly toxic to small mammals on an acute oral basis. Because repeated or continuous avian exposure through persistence, bioaccumulation, or multiple applications, is not expected to occur for IPBC, avian and mammalian reproduction testing is not required. Also because applications of IPBC are not likely to result in exposure to honey bees, non-target insect toxicity data are not required.

The results of the acute toxicity studies indicate that IPBC is very highly toxic to cold-water fish and highly toxic to warm-water fish. IPBC is highly toxic to aquatic invertebrates. Also, IPBC is highly toxic to estuarine/marine fish and highly to very highly toxic to estuarine/marine invertebrates.

Ecological Effects Risk Assessment

Assessment of submitted studies by the Agency indicates that IPBC should not pose a threat to surface water and ground water because it degrades rapidly.

The submitted data indicate that IPBC is slightly toxic to practically nontoxic to birds and very highly toxic to highly toxic to freshwater fish and aquatic invertebrates. While the hazard to aquatic organisms from IPBC has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from the microbicide use of this chemical are regulated under the NPDES permitting program of EPA's Office of Water. All IPBC labeled products must require that discharges to aquatic environments comply with an NPDES permit. Because the outdoor use of IPBC is limited to industrial treatment of forest products, exposure to wildlife is not expected to be significant.

Additional Data Required

EPA is requiring the following additional generic studies for IPBC: guidelines 81-8 and 82-7 to further characterize the potential for IPBC to cause neurological effects; and guidelines 133-3, 133-4, 231, 232, 233, and 234 to characterize exposure to IPBC during wood protection treatment to milled forest products and subsequent handling of treated lumber; exposure to applicators and occupants during and after HVAC treatments; exposure to handlers and consumers of textiles after IPBC treatments, and exposure to non-industrial applicators from IPBC wood treatments by any methods other than brush, roller, and airless or compressed air sprayer. EPA is developing a generic exposure DCI for antimicrobial chemicals.

The Agency also is requiring IPBC product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All IPBC end-use products must comply with EPA's current pesticide product labeling requirements. For a comprehensive list of labeling requirements, please see the IPBC RED document.

Although the Agency is not establishing minimum (baseline) engineering controls for occupational uses of IPBC end-use products, the Agency is establishing minimum (baseline) personal protective equipment for occupational uses of IPBC end-use products. Applicators and other handlers must wear:

- long-sleeve shirt and long pants,
- chemical-resistant gloves,
- shoes plus socks.

Regulatory Conclusion

EPA has determined that products containing IPBC are eligible for reregistration **except** products labeled for industrial wood protection treatment of milled forest products, HVAC uses, textile uses, and non-industrial wood treatments by methods other than brush, roller, and airless or compressed air sprayer. Additional exposure data are being required so that the Agency can assess the risk to workers and handlers from the above-mentioned uses. The Agency cannot make eligibility decisions for these uses at this time.

The use of eligible IPBC products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to IPBC will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for IPBC during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet by using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 1-800-490-9198, fax 513-489-8695.

Following the comment period, the IPBC RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the IPBC RED, or reregistration of individual products containing IPBC, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.